## **REMARKS**

Claims 1-28 are pending. Claims 1-28 are rejected. Specifically, claims 1-7, 10-16, 19-25 and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over US Pub. No. 2002/0175289 to Soluri *et al.* ("Soluri"), in view of US Patent No. 5,099,134 to Hase *et al.* ("Hase") and US Patent No. 4,725,734 to Nishiki, and claims 8, 9, 17, 18, 26 and 27 stand rejected as being unpatentable over Soluri, Hase, Nishiki in view of US Patent No. 5,961,714 to Melcher *et al.* ("Melcher"). These rejections are traversed. Reconsideration of the outstanding rejections in the present application is requested based on the following remarks. <sup>1</sup>

In the first Office Action dated September 8, 2005, claims 1-27 were rejected as being unpatentable over Soluri in view of Hase, and claim 28 was rejected as being anticipated by Hase. In the second Office Action dated April 19, 2006, claims 1-28 were rejected as being unpatentable over Soluri in view of Hase. In the third Office Action (first final action) mailed November 7, 2006, the rejection of claims 1-28 as being unpatentable over Soluri in view of Hase was maintained and made final. In the fourth Office Action dated February 27, 2007, the final rejection of claims 1-28 as being unpatentable over Soluri in view of Hase was withdrawn, and a new ground of rejection of claims 1-28 as being unpatentable over Hase in view of Tang (US Patent No. 5,949,850) and Nishiki was made. In the fifth Office Action (second final action), the rejection of claims 1-28 as being unpatentable over Hase in view of Tang and Nishiki was maintained and made final. An appeal brief was filed and the final rejection of claims 1-28 as being unpatentable over Hase in view of Tang and Nishiki was withdrawn. The Office then inexplicably reverted to the original rejection of claims as being unpatentable over the proposed base combination of Soluri in view of Hase, which was previously withdrawn, while adding Nishiki and newly cited Melcher for their alleged disclosure of secondary features in sixth Office

<sup>&</sup>lt;sup>1</sup> As Applicant's remarks with respect to the Examiner's rejections are sufficient to overcome these rejections, Applicant's silence as to assertions by the Examiner in the Office Action or certain requirements that may be applicable to such rejections (e.g., assertions regarding dependent claims, whether a reference constitutes prior art, whether references are legally combinable for obviousness purposes) is not a concession by Applicant that such assertions are accurate or such requirements have been met, and Applicant reserves the right to analyze and dispute such in the future.

Action dated July 23, 2008. As it was in the responses filed February 8, 2006, and January 9, 2007, October 23, 2008, the proposed combination of Soluri with Hase was traversed as being improper. The Examiner has now issued the third Final Office Action.

As acknowledged by applicants in the specification, Soluri does disclose a collimator with integrated crystals to address alignment problems. However, Soluri's collimator is fabricated by a cumbersome process requiring the formation of elongated holes in a high atomic number material. As admitted in the Office Action, "Soluri fails to expressly disclose the method and/or specifics of producing the collimator..." *Office Action*, p. 4. Hence, the Office Action relies on Hase for teaching the method for producing the collimator and Nishiki for teaching the optically reflecting material coating. However, the Office Action fails to establish a *prima facie* case of obviousness because, *inter alia*, the Office Action fails to provide a proper teaching, suggestion, or motivation to combine the references.

Under KSR, a *prima facie* case of obviousness still requires reasons, based on evidence, to make a proposed combination of references. In KSR, the Supreme Court opposed "a formalistic conception of the words teaching, suggestion, and motivation, or ... overemphasis on the importance of published articles and the explicit content of issued patents" but did not endorse unjustified modification or combination of reference disclosure. *KSR International Col. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). The Federal Circuit subsequently explained:

[A] flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis.... The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence – teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) – that arise before the time of invention as the statute requires.

Ortho-McNeil Pharmaceutical v. Mylan, 2007-1223, \*11 (Fed. Cir. Mar. 31, 2008) (emphasis added). A recent decision by the Board of Patent Appeals and Interferences provides further illumination:

The U.S. Supreme Court recently held that rigid and mandatory application of the "teaching-suggestion-motivation," or TSM, test is incompatible with its precedents. The Court did not, however, discard the TSM test completely; it noted that its precedents show that an invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art."

. . . .

[O]bviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some "apparent reason to combine the known elements in the fashion claimed."

Ex parte Whalen II, Appeal 2007-4423, July 23, 2008, pg. 15-16 (quoting KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1741 (2007)) (citations omitted).

Thus, KSR still requires that a *prima facie* case of obviousness includes *evidence* regarding teachings, suggestions, or motivations to make a proposed combination of references. Such a showing is required to guard against allegations of obviousness that are actually derived from impermissible hindsight.

The Office Action fails to provide proper motivation to make the proposed combination of references. Here, the Office Action provides the Examiner's interpretation of KSR that contradicts both Federal Circuit and BPAI precedent. The only alleged motivation to make the proposed combination of references is from objectives recited in the Summary of the Invention of Hase with the Office Action reciting that:

Hase further teaches that the method making such a collimator improves sensitivity, resolution and manufacturing yields (Col. 1, Lines 45-52). In view of the utility in containing a collimator with such characteristics, it would have been obvious to one of ordinary skill in the art at the time the invention was made to specify that the collimator disclosed in Soluri be made as that taught be Hase.

Office Action, pp. 4-5. The objectives do not provide the proper motivation to form a collimator device including pixellated scintillators individually located in each of said collimation square holes as recited in claim 1 and similarly recited in the other independent claims. Specifically, the Office Action fails to provide evidence that a person having ordinary skill in the art would combine these particular references. Without such an explanation, the proposed combination of references constitutes impermissible hindsight.

As the Examiner knows, hindsight reconstruction of the claimed invention is not a proper basis upon which to make a determination of obviousness under 35 U.S.C. § 103. The teaching, suggestion or motivation instead must come from the prior art itself. The asserted motivation

consists of broad, general statements of providing a "new and improved" collimator do not constitute the specific reasoning to combine different prior art references that would make the proposed combination of references obvious within the meaning of 35 U.S.C. § 103. Clearly, improved sensitivity, high resolution and improved manufacturing yield are universally desired objectives in the medical imaging field, yet does not mean that one of ordinary skill in the art would have sought to modify every collimator in existence with the Hase reference simply because Hase articulated these objectives in the context of his invention.

Moreover, the references actually *teach away* from their combination because Hase discloses a collimator which functions to focus radiation in a converging manner onto a scintillator (note fan-beam focusing slits 3, Fig. 1) and not on pixellated scintillators as required by the independent claims of the present application. Rather, Hase discloses the use of a radiation transparent collimation frame bottom element 12 (Fig. 4; col. 4, lines 29-30). Manifestly, the only reason for making the bottom frame 12 radiation transparent is to allow radiation to pass through and out of the collimator frame to a scintillator positioned adjacent to the collimator. Hence, Hase teaches away from a collimator device having pixellated scintillators.

KSR does not permit rejection of claims based on any arbitrary combination of references; rather, some reason to *combine particular references* must be provided, particularly when these references teach away from their combination. Accordingly, the combination of references is improper and the obviousness rejection should be reversed.

In addition, Hase does not recognize any deficiency in the Soluri device that would be solved by the Hase device. Therefore, Hase contains no teaching, suggestion or motivation from which those of ordinary skill in the art would have sought to make the modification proposed in the Office action. Only the present application teaches an improvement in pixellated collimator fabrication, and only a reading of the present application would have suggested the combination of prior art as set forth in the Office Action.

One of ordinary skill in the art would not have been motivated by Hase to have modified the Soluri miniaturized scintigraphic device as proposed by the Office Action. In this regard, Applicants' argument is **not** that features of one reference may not be bodily incorporated into the other reference, but that no combination of Soluri with Hase would make obvious to one of ordinary skill in the art the invention as set forth in the claims pending in this application.

Hase does not suggest placement of individual crystals between the septa of the disclosed collimator. As previously explained, Hase teaches the requirement of a box frame 13 as shown in Fig. 5, with walls 9 and transparent bottom frame element 12, as a necessary structural requirement of the disclosed collimator. Therefore, the collimator of Hase is intended to be used, and in fact must be used, with a scintillation crystal slab. There simply is no suggestion or teaching in Hase of any other use of the disclosed collimator.

The alleged "teaching" of Hase to improve the manufacturing yield of a <u>conventional</u> mass-produced collimator does not provide the requisite suggestion in the art to modify the specialized, miniaturized device disclosed by Soluri. It is axiomatic that a prior art reference must be considered as a whole for what it discloses to those skilled in the art, and thus it is improper to take individual statements such as the quoted statement out of the context of the prior art reference as a whole. Hase considered as a whole simply does not suggest placement of individual crystals between septa as disclosed by the specialized device of Soluri. Improvement in manufacturing yield of a mass-produced collimator simply does not suggest making any modification to a niche product as disclosed by Soluri. A manufacturer of the Soluri device would not be anxious about improving manufacturing yield as the Soluri device does not have the mass demand of a conventional-use collimator as disclosed by Hase.

Lastly, modifying Hase to use pixellated scintillators would change the principle operation of Hase and modifying Soluri to use the septa requiring a box frame with a transparent bottom frame element would change the principle operation of Soluri. As recited in the MPEP,

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing.

Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

MPEP 2143.01 (VI). Hence the teachings of the references are not sufficient to establish a *prima facie* case of obviousness.

While Nishiki discloses coating collimator plates with a reflector, Nishiki does not suggest the modification of Soluri with Hase as proposed. Accordingly the addition of Nishiki does not render the combination of Soluri with Hase proper as proposed. Similarly, Melcher, cited to support the Office action's proposition that TiO<sub>2</sub> and MgO are known as reflecting materials, fails to make the basic combination of Soluri with Hase obvious or proper. Accordingly, no addition of Melcher with the base references could make the claimed invention obvious.

Thus for at least these reasons, the undersigned representative requests that the rejections of claims 1-28 be withdrawn.

<sup>2</sup> It is not apparent where Melcher, directed to the growth of scintillation crystals, anywhere mentions TiO2 or MgO, as reflecting materials or otherwise.

## **Conclusion**

For the foregoing reasons claims 1-28 are respectfully submitted to be patentable over Soluri in view of Hase, Nishiki and Melcher. Favorable reconsideration of this application and the issuance of a Notice of Allowance are earnestly solicited.

Please charge any fee or credit any overpayment pursuant to 37 CFR 1.16 or 1.17 to Novak Druce Deposit Account No. 14-1437.

RESPECTFULLY SUBMITTED,							
NAME AND REG. NUMBER	Vincent M. Del Attorney for Ap Registration No	Attorn	Thomas A. Corrado Attorney for Applicants Registration No. 42, 439				
SIGNATURE	Thom A. Cound			DATE	1	30 March 2009	
Address	Novak, Druce, DeLuca + Quigg LLP						
	1300 I Street, N.W., Suite 1000 West Tower						
City	Washington	State	D.C.		Zip Code	20005	
Country	U.S.A.	Telephone	202-659-0	100	Fax	202-659-0105	